Institutional Review Board
Ethics and Human
Subject Protections

Overview
Composition of an IRB
Function of an IRB
Understanding of trigger events
Ethical Milestones
IRB types
Consent forms
Trigger events and ethics

Why Do Human Research Subjects Need Protection?

<table>
<thead>
<tr>
<th>Trigger Events</th>
<th>Ethical Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nuremberg War Crimes</td>
<td>Nuremberg Code 1947</td>
</tr>
<tr>
<td></td>
<td>* Belmont Report 1978</td>
</tr>
<tr>
<td></td>
<td>* Common Rule 1991</td>
</tr>
</tbody>
</table>
Nuremberg War Crimes

WWII
Nuremberg, Germany
Horrific experiments were carried out with prisoners

The Belmont Report

The principles of the Belmont Report govern all research supported by the U.S. Government. The ethical principles outlined in the report are the basis for subsequent regulations designed to ensure protection of human subjects in research.
The Basic Principles of the Belmont Report

1. Respect for Persons

2. Beneficence

3. Justice
Respect for Persons

• Treat individuals as autonomous agents

• Do not use people as a means to an end

• Allow people to choose for themselves

• Provide extra protections to those with diminished autonomy (i.e., Prisoners, Children, Cognitively Impaired, etc.)

Beneficence

The two general rules formulated from the principle of beneficence are:

• First, do no harm
• Second, maximize possible benefits and minimize risks
Justice

- Treat people fairly
- Fair sharing of burdens and benefits of the research

An injustice occurs when:

1. benefits to which a person is entitled are denied without good reason, or
2. when burdens are imposed unduly.

Rules and Research

Respect
- Informed Consent Process
- Respect for Privacy

Beneficence
- Good research design
- Competent investigators/researchers
- Favorable risk-benefit analysis

Justice
- Equitable selections of subjects
The "Common Rule" is the set of regulations which were developed to ensure compliance with the principles of the Belmont Report.

The regulations fall under the Department of Health and Human Services.

These regulations have been adopted by many other federal departments which regulate human research.

Protective mechanisms established by The Common Rule

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects
IRB Function

(Institutional Review Board)

To ensure the rights and welfare of human subjects involved in research are adequately protected.

IRB

(Institutional Review Board)

Abides by Department of Health and Human Services guidelines

2013 Members:
Steph charg (Psychology) – chair
Suzanne Collins (Nursing)
Ryan Cragun (Sociology)
Bella Galperin (Business)
Scott Paine (Communications/GWA)
Dr. Linda Taggart, faculty at St. Leo in the Religion/Ethics department.
IRB committee
(Institutional Review Board)

- Mix of genders
- Difference disciplines; scientific and nonscientific
- Each IRB shall have at least five members

IRB Review
(Institutional Review Board)

An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy
Informed Consent

1. They are participating in a research study.
2. The purpose of the research.
3. What they will be asked to do if they agree to participate.
4. How long it will take.
5. How the confidentiality of the information they provide will be protected.
6. Their participation is voluntary.
7. They can refuse to answer questions that they do not wish to answer, and they can refuse to participate or withdraw at any time without penalty or repercussion.
8. How they can contact the principal investigator and the co-investigator(s) should they have questions or concerns about the research.
9. Your affiliation with the University of Tampa
Debriefing Statement

After the study the experimenter debriefs the participant either orally or in writing. The debriefing contains:

1. A statement thanking the subject for participating.
2. A statement of the purpose of the study – the hypothesis/research questions being investigated and results expected.
3. Information about when and where results will be available.
4. Information about whom to contact should there be further questions or should the person experience undesirable consequences from participating. This should include the principal investigator and the IRB chair and may include hotlines, counseling centers and other support contacts.

Example

Thank you for participating in this research study entitled, “Environmental and Health Scan of Hookah Bars: A Policy Initiative.

This study has been approved by the University of Tampa Institutional Review Board.

If you have any questions about this study please call Dr. Martinasek at: 813-257-5037
IRB Review of Research

- Full
- Expedited
- Exempt
- Research Not Involving Human Subjects

- One or more Committee member(s) are assigned to review the complete protocol or amendment, consent form, Investigational Drug/Device Brochure and any other protocol materials.
- These Primary & Secondary Reviewers summarize the protocol or amendment to the Full Committee at a convened meeting and answer questions during the discussion.
- All other committee members are provided with summary information, for example the Protocol Cover Form and informed consent document. *This stresses the importance of the accuracy and details provided in these documents, since the majority of voting members only see these 2 documents!*

Full Review
• Protocols, amendments, or continuing reviews that meet specific federal criteria qualify for an expedited review.
• The complete protocol, consent form, and any other protocol materials receive review and approval by a Committee Chair.
• Expedited does not mean “fast” it is a federal term used for research that must meet specific criteria (DHHS 45 CFR 46.110)

Expedited Review

• Committee review is not required for certain categories of research activities that involve little or no risk to human subjects.

• To determine if your research qualifies for exemption from formal committee review, complete the “Protocol Exemption Review and Determination Checklist.”
• Only the IRB can make the determination of Exempt, this cannot be determined by researchers!

Exempt from IRB Review
Criteria for IRB Approval

- Risks are Minimized (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- Risks are Reasonable in Relation to Benefits
- Selection of Subjects is Equitable
- Informed Consent will be Sought for Each Prospective Subject
- Informed Consent will Be Documented
- Research Plan Adequately Provides for Monitoring the Data Collected to Ensure Safety of the Subjects
- Research Plan Adequately Protects the Privacy of Subjects and Maintains Confidentiality
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects.

The IRB has the authority to:

- Approve
- Require modifications prior to approval
- Table
- Disapprove all research activities including proposed changes in previously approved human subject research.